

Appl. No. 10/036,308

Amendment dated December 2, 2004

Reply to Office Action dated August 2, 2004

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1-3. (Cancelled)

4. (Currently amended) A method for diagnosing Alzheimer's disease comprising:

- (a) obtaining blood or cerebrospinal fluid from a subject;
- (b) ~~detecting~~ determining the amount of human kallikrein 6 ("hK6") in said blood or cerebrospinal fluid; and
- (c) comparing said amount of hK6 detected to an amount for healthy control subjects, where detection of a statistically significant increase of hK6 compared with an amount for the healthy control subjects is indicative of Alzheimer's disease.

5. (Currently amended) A method for diagnosing Alzheimer's disease ~~as claimed in claim 4~~ comprising:

- ~~(a) obtaining blood or cerebrospinal fluid from a subject;~~
- ~~(a b)~~ contacting the blood or cerebrospinal fluid with an antibody specific for hK6 which is directly or indirectly labelled with a detectable substance;
- ~~(b c)~~ detecting determining the hK6 by measuring the amount of the detectable substance in the blood or cerebrospinal fluid;
- ~~(e d)~~ comparing the amount of hK6 to an amount obtained for samples from healthy control subjects where a statistically significant increase in the amount of hK6 compared with the amount for the healthy control subjects is indicative of Alzheimer's disease.

6. (Currently amended) A method for the diagnosis of Alzheimer's disease ~~as claimed in claim 4~~ comprising:

- ~~(a) obtaining blood or cerebrospinal fluid from a subject;~~

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- (a ~~b~~) incubating the blood or cerebrospinal fluid with a first antibody specific for hK6 which is directly or indirectly labeled with a detectable substance, and a second antibody specific for hK6 which is immobilized;
- (b ~~c~~) separating the first antibody from the second antibody to provide a first antibody phase and a second antibody phase;
- (e ~~d~~) ~~detecting~~ determining the hK6 by measuring the amount of the detectable substance in the first or second antibody phase; and
- (d ~~e~~) comparing the amount of hK6 with an amount obtained for samples from healthy control subjects where a statistically significant increase in the amount of hK6 levels compared with the amount for the healthy control subjects is indicative of Alzheimer's disease.

7-8. (Cancelled)

9. (Currently amended) A method as claimed in claim 6 wherein in step ~~[(a)]~~ (b) the first and second antibodies are contacted simultaneously or sequentially with the blood or cerebrospinal fluid.

10. (Previously presented) A method as claimed in claim 5 wherein the antibody is a monoclonal antibody, a polyclonal antibody, immunologically active antibody fragments, humanized antibody, an antibody heavy chain, an antibody light chain, a genetically engineered single chain F_v molecule, or a chimeric antibody.

11. (Previously presented) A method as claimed in claim 5 wherein the detectable substance is alkaline phosphatase.

12. (Previously presented) A method as claimed in claim 11 wherein the alkaline phosphatase is detected using a fluorogenic substrate.

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13. (Previously presented) A method as claimed in claim 12 wherein hK6 is detected determined using time-resolved fluorescence.